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(71) Applicant: **AVERY INTERNATIONAL CORPORATION**
P.O. Box 7090
Pasadena California 91109(US)

(72) Inventor: **van Soom, Petrus Ludovicus Augustinus Maria**
Dopheistraat 4
B-2350 Vosselaar(BE)

(74) Representative: **Kooy, Leendert Willem et al OCTROOIBUREAU VRIESENDORP & GADE**
P.O. Box 266
NL-2501 AW The Hague(NL)

(54) **Weldable microporous non-woven tape for medical applications.**

(57) The present invention relates to a microporous non-woven tape to be adhered to human skin by means of an adhesive layer harmless to the skin, providing the unique combination of both moisture-vapour permeability and hydrostatic-pressure resistance. Said tape may also be welded to a thermoplastic film. This product is highly suitable to be used as self-adhesive flange for stoma bags.

The product comprises a porous, woven or non-woven web of paper, synthetic or natural fibers, to which an adhesive coating layer is applied and the product is coated and/or impregnated with a thermoplastic material and surfactant in such a way that it has a moisture vapour transmission rate independent of the direction of at least 150 g/m²/24h at 37°C and at the same time is withstanding a hydrostatic column of a 0.9% NaCl/H₂O solution of 11.5 cm height for at least 20 seconds without leakage, said product optionally being covered by a protective release liner.

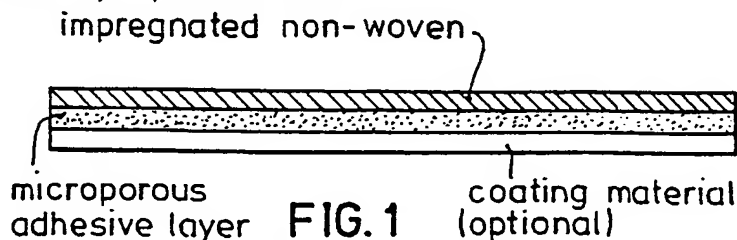


FIG. 1

Weldable microporous non-woven tape for medical applications.

The present invention relates to a microporous non-woven tape to be adhered to human skin by means of an adhesive layer harmless to the skin, providing the unique combination of both moisture-vapour permeability and hydrostatic-pressure resistance that is to say it provides a liquid barrier. Said tape may also be welded to a thermoplastic film. This product is highly suitable to be used as self-adhesive flange for stoma bags. Beside the use of a self-adhesive welding flange for stoma bags, this product is also suitable for the use as surgical plaster due to its vapour permeability, so that no moist film will occur between the adhesive layer and the human skin which would result in a loss of adhesive qualities and an uncomfortable feeling for the person, and in a loss of the liquid barrier, so the mechanical qualities of non-woven tape are maintained and a bacterial barrier is produced, so that the risk of exogeneous bacterial infection to such a plaster-covered wound is minimized.

Another application is the use of said tape adhered to human skin, including the optimal use of thermoplastic auxiliaries fused upon the non-adhered side such as for example an electrocardiogram electrode.

The numerous kinds of commercially available stoma bags for both colostomia- and ileostomia patients consist of a self-adhesive, non-woven flange which has as a function that the stoma bag can be attached to the stoma with a self-adhesive tape construction. Self-adhesive non-woven tapes are also commercially available, said tapes show a certain MVTR (=moisture-vapour transmission rate), to allow constant breathing of the skin when covered with tape. However, this implies that an open construction is to be made which has as a drawback that this is hardly or not moisture proof, in other words water from the outside contacting the tape, for example when the stoma patient with the stoma bag adhered to the skin would take a shower or bath.

An internal market study of a number of European ostomia bags' manufacturers showed that there is a demand for self-adhesive non-woven tape meeting the following requirements:

- non-irritating pressure-sensitive adhesive
- moisture vapour permeable non-woven tape
- moisture repellent non-adhered side
- non-adhered side fusible by means of heat, and/or high frequency radio waves to a thermoplastic film
- strong i.e. hard to tear, but flexible non-woven tape.

Due to the fact that the thermoplastic film can be welded to the non-adhered side of the non-woven

tape, the stoma-bags' manufacturer is in a position to produce the stoma bag in a more efficient and economical way.

Microporosity and moisture vapour permeability can be measured in various ways and a possibility is to measure the amount of air expressed in ml/min by a known surface at a certain pressure. However, the most relevant and practice-based test, is measurement of the MVTR (moisture vapour permeability rate) expressed in $\text{g H}_2\text{O}/\text{m}^2/24 \text{ h}$ at 37°C . The water-repellency may be measured by means of water retention in the non-woven after its immersion. Another method to measure the water repellency is to measure the time up to leakage caused by a static liquid column of a specified height positioned on the tape.

The singular feature of the invention is the balance of on the one hand the moisture vapour permeability and on the other hand the liquid barrier which look contradictory.

A microporous construction will show a high MVTR, but otherwise will have quite a low water barrier. A high water barrier can be achieved by sealing the non-woven completely by means of a film, but then a very low MVTR will be achieved.

By treating the non-woven with a water-repellent agent and subsequently coating the non-woven with a microporous adhesive, this unique combination is achieved. In case the MVTR is plotted as a function of the liquid barrier a line is obtained which dependent on the microporosity of the adhesive layer, the degree of water repellency which can be obtained via a plurality of techniques, and the density of the non-woven, will shift to the right to a limit as described herebelow. By an appropriate selection of the applied materials it is also possible to prepare the non-adhered side of the non-woven for welding to a thermoplastic film.

The invention relates to a laminated product characterized in that the product comprises a porous, woven or non-woven web of paper, synthetic or natural fibers to which an adhesive coating layer is applied and the product is coated and/or impregnated with a thermoplastic material and surfactant in such a way that it has a moisture vapour transmission rate independent of the direction of at least $150 \text{ g}/\text{m}^2/24\text{h}$ at 37°C and at the same time is withstanding a hydrostatic column of a 0.9% NaCl/ H_2O solution of 11.5 cm height for at least 20 seconds without leakage, said product optionally being covered by a protective release liner.

A preferred product is characterized in that the product has either a liquid barrier between 20 and 350 seconds measured with a 11.5 cm static liquid column of a 0.9 NaCl/ H_2O solution and a moisture-

vapour permeability between 150 and 3000 g/m² 24 h at 37° C or a liquid barrier between 350 and 1000 seconds measured with a 11.5 cm static liquid column of a 0.9% NaCl/H₂O solution and a moisture permeability between 150 and 1400 g/m² 24h at 37° C.

Preferably the non-adhered side of the product is weldable to a synthetic film by means of heat, high frequency radio waves or ultrasonic techniques.

The thermoplastic material is preferably polyvinyl acetate.

The surfactant is preferably fluorocarbon.

Examples

The present invention can be achieved in various ways discussed here below in detail. A final selection of production depends on the various technical possibilities.

1) A first possibility comprises the impregnation, spraying or foam-coating of a non-woven with an emulsion consisting of a fluorocarbon providing the water-repellency of the total construction and a polyvinyl chloride or polyvinyl acetate to make it possible in the final application to weld thermally by means of heat or high frequency radio waves a thermoplastic copolymer film of ethylvinyl acetate/polyethylene or a coextruded film consisting of polyvinylidene chloride/polyethylene to the treated non-woven. In a second step a microporous pressure-sensitive adhesive layer harmless to the skin is attached to the non-woven by means of a direct or transfer coating.

Producing a microporous adhesive can be done chemically by starting a chemical reaction for gas-producing after applying the adhesive layer to the support. A physical way is mixing air or an inert gas in the adhesive prior to or during the coating of the support with the adhesive layer. In both cases micropores are produced in the adhesive layer to provide the porous character. The whole construction may optionally be coated with siliconized coating material dependent on the final use and/or used coating technique (vide fig. 1).

MVTR values of the material may vary of about 1000 to 3000 g/m² 24h/ at 37° C and a water repellency measured with a 11.5cm high liquid column of a 0.9% NaCl/H₂O solution of some seconds to minutes dependent on the thickness of the adhesive layer, the absolute adhesive area i.e. microporosity percentage and the density of the non-woven. A typical example is the impregnation of a 35 g/m² 100% polyamide spunlaid non-woven with an emulsion consisting of a fluorocarbon and polyvinyl acetate.

Thereeto a 30 g/m² microporous polyacrylate

adhesive is applied by means of a transfer coating technique. The tape construction shows a MVTR of 2900 g/m² 24h at 37°C and a water repellency of 180 sec.

2) A second possibility is the coating with a roller- or extrusion coating of a thermoplastic material, in this case ethylvinyl acetate on a non-woven. However, this has to provide a non-closed film to be obtained by a correct selection of the applied amount and the coating temperature. In order to obtain penetration of the coating into the non-woven, to produce a non-closed film. Subsequently a microporous layer can be applied to the non-coated side of the non-woven as described above sub 1). The water-repellency can be enhanced by treating the non-woven in a preceding step with a surfactant, e.g. fluorocarbon (vide fig. 2).

An example of said method is applying a 25 g/m² hot melt EVA by means of a die-coating to a water-repellent 35 g/m² 100% polyamide spunlaid non-woven, thereafter applying a 30 g/m² microporous polyacrylate adhesive to the non-EVA coated side with a transfer-coating technique. By means of this technique identical values can be obtained as described sub 1). Here it is also possible dependent on the final application to change the MVTR and/or water barrier dependent on the selection of the thickness of the adhesive layer, the absolute adhesive area i.e. microporosity, the density of the non-woven, the water-repellency of the non-woven, and the thickness/sealing of the EVA coating layer.

3) A third possibility is the application of a perforated thermoplastic film to the non-woven. This application may take place by means of heat, and/or pressure-lamination or by adhering. However, the adhesive medium should be a non-closed layer, because otherwise the result is a too closed construction with too low a MVTR. Therefore it is recommendable to apply the adhesive layer in a grit pattern.

In a further step a microporous adhesive layer is also applied as described sub 1). Optionally the liquid barrier may further be enhanced by using a water-repellent non-woven (vide fig. 3).

An example of the above described manner is heat laminating of a 25 microns 60 mesh/100 microns average perforated polyethylene film on a water-repellent 35 g/m² 100% polyamide spunlaid non-woven.

In a further step a 30 g/m² microporous polyacrylate adhesive layer is applied to the non-laminated side of the non-woven. Characterizing values are a MVTR of 2900 g/m² 24h at 37°C and a water-repellency of 180 sec.

An alternative method is heat lamination and/or pressure lamination, or by extrusion of a sealed thermoplastic film on the non-woven, and in a fur-

ther step this laminate is physically microperforated with e.g. a needle roller, laser beam, or a high-pressure water jet. Subsequently a microporous adhesive layer optionally covered with a protective release liner is applied to said treated laminate.

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Claims

1. Laminated product characterized in that the product comprises a porous, woven or non-woven web of paper, synthetic or natural fibers, to which an adhesive coating layer is applied and the product is coated and/or impregnated with a thermoplastic material and surfactant in such a way that it has a moisture vapour transmission rate independent of the direction of at least $150 \text{ g/m}^2/24\text{h}$ at 37°C and at the same time is withstanding a hydrostatic column of a 0.9% NaCl/ H_2O solution of 11.5 cm height for at least 20 seconds without leakage, said product optionally being covered by a protective release liner.

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2. Product according to claim 1, characterized in that the product has either a liquid barrier between 20 and 350 seconds measured with a 11.5 cm static liquid column of a 0.9 NaCl/ H_2O solution and a moisture-vapour permeability between 150 and $3000 \text{ g/m}^2/24\text{h}$ at 37°C , or a liquid barrier between 350 and 1000 seconds measured with a 11.5 cm static liquid column of a 0.9% NaCl/ H_2O solution and a moisture permeability between 150 and $1400 \text{ g/m}^2/24\text{h}$ at 37°C .

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3. Product according to claim 1-2, characterized in that its non-adhesive side is weldable to a synthetic film by means of heat, high frequency radio waves or ultrasonic techniques.

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4. Product according to claim 1-3, characterized in that the thermoplastic material is polyvinyl acetate.

5. Product according to claim 1-4, characterized in that the surfactant is fluorocarbon.

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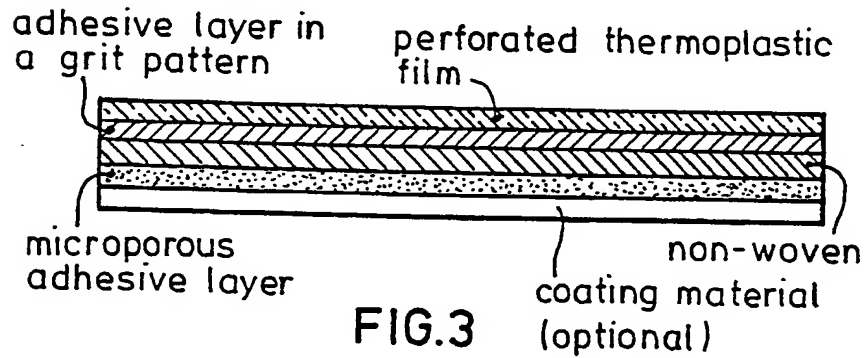
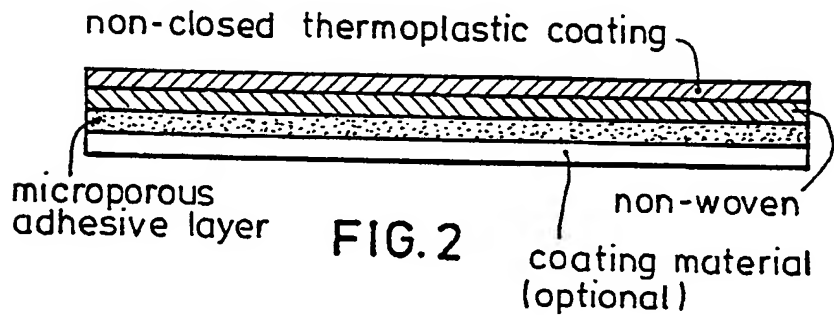
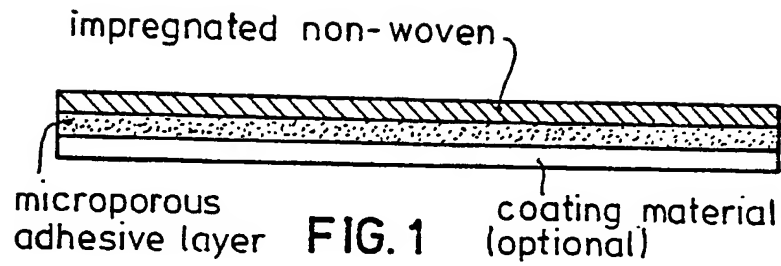
6. Product according to claim 1-5, characterized in that it can be used as self-adhesive flange for stoma bags.

7. Product according to claim 1-6, characterized in that it can be used as surgical plaster tape, and accessories are welded to the non-adhered side.

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EP 88 20 1036

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
A	GB-A- 448 164 (SANDER'S CHEMICAL PRODUCTS LTD) * Lines 30-34,74-81 *	1	A 61 F 13/02
A	EP-A-0 081 987 (McCRACKEN et al.) * Claim 1 *	1	
A	US-A-3 645 835 (HODGSON) * Column 1, lines 25-37; column 6, lines 17-26 *	1	
P,A	EP-A-0 257 133 (EWALL) * Claims 1,2 *	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
			A 61 F A 61 L
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 25-08-1988	Examiner GLAS J.
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document	